Complete Summary

GUIDELINE TITLE

Laparoscopic surgery for cancer of the colon: a clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Smith A, Rumble RB, Langer B, Stern H, Schwartz F, Brouwers M, Laparoscopic Colon Cancer Surgery Expert Panel and Program in Evidence-based Care. Laparoscopic surgery for cancer of the colon. Toronto (ON): Cancer Care Ontario (CCO); 2005 Sep. Various p. (Evidence-based series; no. 2-20-2). [13 references]

GUIDELINE STATUS

This is the current release of the guideline.

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COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Colon cancer

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Gastroenterology
Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

Clinical Issues

To evaluate if laparoscopic surgery can be recommended as an alternative to conventional open surgery for patients with stages I, II, or III colon cancer (not rectal cancer) based on a comparison of outcomes

Professional Practice Issues

To evaluate what experience and training surgeons should have who perform laparoscopic surgeries for cancer of the colon

Institutional and Organizational Issues

To evaluate the recommended criteria for institutions performing laparoscopic surgeries for cancer of the colon

TARGET POPULATION

Adult patients with stage I, II, or III colon cancer (not rectal cancer) who do not have perforation, obstruction, fistula, or attachment to other structures (locally advanced disease)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Conventional open colon surgery
2. Laparoscopic colon surgery

MAJOR OUTCOMES CONSIDERED

Primary outcomes of interest include:

- Survival
- Recurrence
- Adverse event rates

Secondary outcomes of interest are:

- Operating time
- Time until hospital discharge

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

The MEDLINE (1985 to July week 4 2004), CANCERLIT (1986 to March 2001) and Cochrane Library's Evidence-based Systematic Reviews (through 2004, Issue 2) databases were searched using the Medical Subject Headings colonic neoplasms/surgery and the keywords cancer and colon both combined with the keyword laparoscopy. Ongoing clinical trials were identified using the National Cancer Institute (NCI) database on the Internet (http://www.cancer.gov/search/clinical_trials/). Relevant articles were selected and reviewed by two reviewers, and the reference lists from those sources were searched for additional trials. The reference lists from review articles were also searched for relevant evidence.

Study Selection Criteria

Eligible Studies

1. Randomized controlled trials (RCTs) comparing laparoscopic colon surgery to conventional open surgery
2. Systematic Reviews (including meta-analyses and practice guidelines)
3. Papers published in English only

Exclusion Criteria

1. In the trials, the majority of patients were treated for conditions other than cancer, or the proportion of colon or rectal cancer patients was not clearly described or indicated.
2. Abstracts
3. Letters and editorials describing trial results

NUMBER OF SOURCE DOCUMENTS

Five fully published randomized controlled trials (RCT) reports met the selection criteria and form the body of evidence for this report.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

As the results were obtained from fully published trial reports, individual patient data were not available for review. All the primary outcomes (overall survival, recurrence, and adverse event rates) could be synthesized via meta-analysis. For each comparison, the number of patients randomized to each treatment arm was used as the denominator, except where only the number of evaluable patients was provided. Survival data were pooled at the reported time of follow-up, which varied across trial reports. Combining data this way assumes a constant hazard of risk within the groups being compared over time; however this assumption was not tested. Data were pooled using the meta-analysis software package Review Manager (RevMan version 4.2.1, 9 April 2003) (The Cochrane Collaboration, Oxford, England). Results are expressed as the relative risk ratio (RR), where an RR < 1 favours the treatment group, and an RR > 1 favours the control group. Data were analyzed using the random effects model as the more conservative estimate of effect, and expressed with a 95% confidence interval (CI). Insufficient data were available to allow for appropriate pooling of the secondary outcomes (operating times and time until hospital discharge); ranges and overall unweighted means are reported. Weighted means could not be properly calculated because standard deviations were not reported in the studies.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Provincial Panel Consensus Process

Members of the Laparoscopic Colon Cancer Surgical Expert Panel (LCCSEP) agreed unanimously with the interpretation of the evidence. For patients with colon cancer within the well-defined target population, laparoscopic surgery should be considered a treatment option based on the findings of no statistically significant differences for overall survival, recurrence, and adverse effects when compared with open surgery.

The main topic of discussion within the membership involved determining the proposed minimum standards for clinicians. The minimum number of prior procedures recommended in the Hazelbroek et al and Clinical Outcomes of Surgical Therapy (COST) trials were thought to be poorly defined and the true threshold for equivalent patient outcomes might well be less than 20; therefore, stating any minimum as the absolute standard of practice was seen as potentially limiting capable surgeons. To impose such a limitation without providing some plan of action detailing training and accreditation procedures would be viewed as restricting practice.

Disease Site Group Consensus Process

The draft guideline (version date February 21, 2005) was reviewed and discussed by the Gastrointestinal Cancer Disease Site Group (DSG) on February 25, 2005. All members were in agreement regarding the following interpretation of the evidence: based on the evidence currently available there is no statistically significant difference between laparoscopic surgery (LAP) and conventional open surgery (CON) when used for resection with curative intent in the treatment of Stages I,II, or III colon cancer, with respect to overall survival and recurrence. However, significant differences were detected between LAP and CON surgery for length of hospital stay (favouring LAP) and duration of surgery (favouring CON).

The Gastrointestinal Cancer Disease Site Group agreed with the draft recommendations and motioned that the document be sent out for practitioner feedback.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practitioner feedback was obtained through a mailed survey of 319 clinicians (comprised of general surgeons, gastrointestinal surgeons, gastroenterologists, etc.) and 121 administrators (hospital chief executive officer's [CEO's], etc) in Ontario, Canada, for a total of 440 potential respondents. The survey consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a practice guideline. Written comments were invited. The practitioner feedback survey was mailed out on June 8, 2005. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The

Laparoscopic Colon Cancer Surgery Expert Panel (LCCSEP) and the Gastrointestinal Cancer Disease Site Group (DSG) reviewed the results of the survey.

The final Evidence-based Series report was reviewed and approved by the Program in Evidence-based Care (PEBC) Report Approval Panel (RAP), which consists of two members including an oncologist, with expertise in clinical and methodological issues.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Clinical Issues

Based on the clinical evidence, a consensus of expert opinion, and the experience of members of the Laparoscopic Colon Cancer Surgery Expert Panel (LCCSEP), the following is recommended:

- Laparoscopic surgery is recommended as an acceptable option for the treatment of stage I, II, or III colon cancer and should be considered an alternative to conventional open surgery for colon cancer in specified patients.

Professional Practice Issues

- The Laparoscopic Colon Cancer Surgery Expert Panel recommends that surgeons should have completed a number of laparoscopic colectomies to a level of accepted competence, as determined by their peers in a structured mentoring process. The best evidence available indicates that primary outcomes are not statistically different between laparoscopic and open surgery for colon cancer after at least one member of the team has performed 20 laparoscopic colon resections, for either benign or malignant disease. Therefore, it is recommended that either this number be adhered to or an equivalent process, including peer evaluation, be undertaken.
- Surgeons are strongly encouraged to self-audit their experiences. The use of audit tools such as that championed by the Canadian Association of General Surgeons (CAGS) is recommended.

Institutional and Organizational Issues

- The Laparoscopic Colon Cancer Surgery Expert Panel recommends that all eligible institutions should show a commitment to advanced laparoscopic surgery by providing appropriate equipment, operating room time, and human resources, including developing a team approach to maximize the experience and efficiency of all team members.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by randomized controlled trials.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Clinical Issues

- Pooling data from two randomized controlled trials involving 1,071 patients did not detect a statistically significant difference between laparoscopic surgery and open surgery for survival (85% versus 83%, respectively).
- Pooling data from two randomized controlled trials involving 1,071 patients did not detect a statistically significant difference between laparoscopic surgery and open surgery for recurrence (17% versus 21%, respectively).
- Data analyses from four randomized controlled trials each detected a statistically significant difference between laparoscopic surgery and open surgery for operating times in favour of open surgery (unweighted mean across studies: 163 minutes versus 111.5, respectively).
- Data analyses from four randomized controlled trials each detected a statistically significant difference between laparoscopic surgery and open surgery for time to hospital discharge in favour of laparoscopic surgery (unweighted mean across studies: 5.1 days versus 7.3 days, respectively).

POTENTIAL HARMS

Three of the five trials provided poolable data on adverse events. These events were not graded; the numbers pooled were the actual number of events reported in each trial. The trial by Stage et al did not report adverse events by treatment arm, and no adverse events were reported by Hazelbroek et al for the colon carcinoma laparoscopic or open resection (COLOR) trial. A summary of adverse event data appears in Table 2 in the original guideline document. A pooled analysis was planned where the number of adverse events reported in each treatment arm was compared. Pooling the data did not detect a statistically significant difference between laparoscopic surgery and open surgery for the incidence of adverse events, relative risk ratio (RR) = 0.52 (95% confidence interval (CI), 0.19, 1.37; p=0.18). Significant statistical heterogeneity was detected in this comparison (p=0.002), but interpretation was not affected as the outcome was not significant.

CONTRAINDICATIONS

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Possible contraindications to performing a laparoscopic colon resection include general contraindications applicable to colon surgery in general, those applicable to other laparoscopic procedures in general, or those specific to a subgroup of

patients. Previous colon resection, significant obesity, or another major medical illness represent relative contraindications and should only be approached by experienced laparoscopic colorectal surgeons.

QUALIFYING STATEMENTS

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Clinical Issues

- The patient population to whom this guideline applies was the standard population studied in the randomized controlled trial reviewed.
- These recommendations do not apply to patients with colon cancer associated with perforation, obstruction, fistula, or attachment to other structures (locally advanced disease).
- The recommendations do not apply to patients with rectal cancer as evidence is unavailable for this population.

General

- This report provides clinical, professional, and organizational advice regarding the role of laparoscopic surgery for adult patients with stages I, II, or III colon cancer for whom surgery is the first-line treatment of choice.
- This advice document is intended to assist in clinical decision making and planning for ALL surgeons (general surgeons, colorectal surgeons, etc.) and ALL institutions that treat patients with colon cancer in the Province of Ontario, Canada.
- Care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult the practice guideline is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding their content or use or application and disclaims any for their application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Sep

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Laparoscopic Colon Cancer Surgery Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Dr. Andy Smith, MD, MSc (Chair); Dr. Mehran Anvari, MBChB, PhD; Dr. Melissa Brouwers, PhD; Dr. Patrick Colquhoun, MD, MSc, Mr. Tony Dagnone, CM; Dr. John Hagen, MD; Dr. Bernard Langer, MD; Dr. Angus Maciver, MD; Dr. Robin McLeod, MD; Dr. Eric Poulin, MD; Mr. R. Bryan Rumble, BSc; Dr. Christopher Schlachta, MD, CM; Dr. Marko Simunovic, MD, MPH; Dr. Hartley Stern, MD; Dr. Lee Swanstrom, MD; Ms. Farrah Schwartz, MA

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Laparoscopic Colon Cancer Surgical Expert Panel (LCCSEP) were polled for conflicts of interest, and none were reported.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Laparoscopic surgery for cancer of the colon. Evidence-based Series. Toronto (ON): Cancer Care Ontario (CCO), 2005 Sep. Various p. (Practice guideline; no. 2-20-2). Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.
- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 23, 2006. The information was verified by the guideline developer on February 23, 2006.

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Date Modified: 9/25/2006